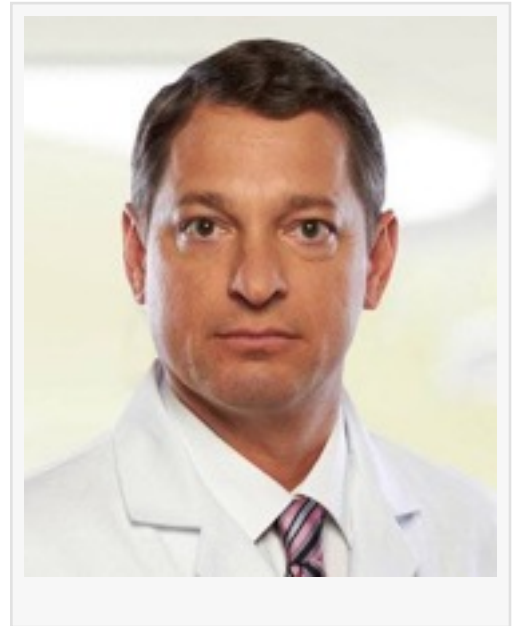


# Bad News for Women: “The Altis Sling...Performance is Consistent with...Predicate Devices”

*Does the Altis sling, like other mini-slings, reduce the risk of obturator and pudendal neuralgia when compared to TVT-O or TOTs?*

SANTA BARBARA, CA, UNITED STATES, June 17, 2020 /EINPresswire.com/ -- Coloplast sponsored an Investigational Device Exemption (IDE) for the Altis sling used in the surgical management of stress urinary incontinence (SUI) to obtain data of safety and efficacy with 113 women and the conclusion was that it “met all end points of the study and its performance is consistent with the legally marketed predicate devices.” Predicate devices are those of the same kind that were already cleared by the FDA to be marketed in the United States. Predicate devices to the Altis included the full length [transobturator](#) (TOT) slings.



Unfortunately, this study did nothing to prove that this device was safe as it did not address the question that represents the elephant in the room in the urogynecology community: Does the Altis sling, like other mini-slings such as the Boston Scientific Solyx sling, reduce the risk of

[obturator](#) and pudendal neuralgia when compared to the likes of the Ethicon TVT-O, Boston Scientific Obtryx, and Coloplast Aris TOTs?

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*Dr. Greg Vigna*

To date the incidence of long-term post-operative groin pain when comparing mini-slings to the TOTs show no statistically significant deference. Thus, the mini-slings failed to reduce the risk of long-term post-operative pain which was the primary reason for their development by

sling manufacturers. Reducing the size of the mesh by having tissue fixation terminal devices that insert into the obturator internus muscle in the pelvis to avoid the muscles and nerves in the groin does not appear to substantially reduce the risk of [chronic pain](#).

Greg Vigna, MD, JD, national pharmaceutical injury attorney, physician, and Certified Life Care Planner states, "The Altis study doesn't report on the question of chronic long-term pain, and basically ignored the elephant in the room. The Aris Coloplast IDE Study is silent on this issue as it doesn't even mention groin pain and reported 'no unanticipated device effects' and 'performance is consistent with the legally marketed predicate devices.' What does 'no unanticipated device effects' even mean? Women with SUI don't need the Altis to perform as other marketed TOTs because we know TOTs are extremely dangerous devices that must be litigated out of the marketplace."

Dr. Vigna adds, "This type of mini-sling is dangerous since a small percentage of women will be catastrophically injured with life-altering pain. The manufacturers know about the occurrence of obturator and pudendal neuralgia but remain silent in their Instructions for Use on how doctors are supposed to manage these foreseeable and unavoidable injuries. Symptoms of serious neurological harm may include new onset painful bladder filling, tailbone pain, anorectal pain, groin pain, dyspareunia, and increased sensitivity to friction on the vulva such women can't wear tight pants."

Dr. Vigna concludes, "We know that TOTs and mini-slings that insert into the obturator internus muscle cause pudendal neuralgia and obturator neuralgia and we have a line of cases forming across the country against Coloplast and Boston Scientific. A small minority in the urology, urogynecology, and gynecology fields know as well, and they don't use mini-slings and TOTs for this reason. We will see to it that Boston Scientific and Coloplast gets the message that their devices are designed defectively under the law and that there are safer alternative designs that don't put the pudendal and obturator nerve in peril."

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome. He has clients filed around the country with Martin Baughman, a Dallas Texas firm. Ben Martin and Laura Baughman are national pharmaceutical injury trial attorneys in Dallas, Texas.

For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal (<https://pudendalportal.lifecare123.com/>) or <https://tvm.lifecare123.com/>.

Click here for information regarding sling related complications:

<https://tvm.lifecare123.com/slidgebook.html>

Click here for a FREE BOOK on Vaginal Mesh Pain: <https://vignallawgroup.com/publications/>

References:

[https://www.coloplast.us/Global/US/SU%20-%20FPH/4%20-SU\\_FPH\\_ALTIS\\_CLINICAL\\_M2462N.pdf](https://www.coloplast.us/Global/US/SU%20-%20FPH/4%20-SU_FPH_ALTIS_CLINICAL_M2462N.pdf)

[https://www.researchgate.net/publication/324236478\\_A\\_systematic\\_review\\_and\\_meta-analysis\\_of\\_single-incision\\_mini-slings\\_MiniArc\\_versus\\_transobturator\\_mid-urethral\\_slings\\_in\\_surgical\\_management\\_of\\_female\\_stress\\_urinary\\_incontinence](https://www.researchgate.net/publication/324236478_A_systematic_review_and_meta-analysis_of_single-incision_mini-slings_MiniArc_versus_transobturator_mid-urethral_slings_in_surgical_management_of_female_stress_urinary_incontinence)

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